Official Title: A Smart Health 3P (Prevention, Protection, Progression) platform for people with physiological and psychosocial distress under the influence of COVID-19

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Approved by the Human Subjects Ethics Sub-committee of
The Hong Kong Polytechnic University on 27th June 2022

CONSENT TO PARTICIPATE IN RESEARCH

(Participant)

A Smart Health 3P (Prevention, Protection, Progression) platform for people with physiological and psychosocial distress under the influence of COVID-19

Principal Investigator: Dr. Justina Yat-Wa Liu
(School of Nursing, The Hong Kong Polytechnic University)

I _____ (Participant's name) hereby consent to participate in the captioned research conducted by Dr. Justina Yat-Wa Liu.

I understand that information obtained from this research may be used in future research and published. However, my right to privacy will be retained, i.e. my personal details will not be revealed.

The procedure as set out in the attached information sheet has been fully explained to me. I understand the benefits and risk involved. My participation in the project is voluntary.

I acknowledge that I have the right to question any parts of the project and/or conversation and can withdraw from the study at any time without penalty of any kind.

_____	_____
Signature of Participant	Signature of Researcher
_____	_____
Name of Participant	Name of Researcher
_____	_____
Date of Signature	Date of Signature

INFORMATION SHEET

A Smart Health 3P (Prevention, Protection, Progression) platform for people with physiological and psychosocial distress under the influence of COVID-19

Principal Investigator: Dr. Justina Yat-Wa Liu
(School of Nursing, The Hong Kong Polytechnic University)

We would like to invite you to take part in a research project conducted by Dr. Justina Yat-Wa Liu, Associate Professor from School of Nursing, The Hong Kong Polytechnic University and her team. This project aims to develop a three-level Smart Health online platform (Prevention, Protection, Progression) and to evaluate its efficacy of alleviating people's physiological and psychosocial distress under the influence of COVID-19.

After participating in the research project, you will undergo a screening process conducted by researchers for eligibility checking. Your information will be collected for research purpose. Study eligibility will be decided based on the following inclusion and exclusion criteria:

Inclusion criteria

- Aged 18 and older；
- Individuals, both COVID-19 victims and non-COVID-19 victims exhibiting physiological and/or psychosocial distress due to the COVID-19 pandemic.
    - Psychological distress refers to excessive negative stress. A cutoff value of ≥ 20 in the Kessler Psychological Distress Scale (K10) will be used to indicate participants with psychological distress.
    - Physiological symptoms related to distress refer to a complaint that one has experienced one of the following symptoms for at least 3 days in the past week: physical fatigue, decreased sleep quality, and pain.
        - Physical fatigue as measured by a cutoff value of ≥ 4 on the Brief Fatigue Inventory (BFI); or
        - Decreased sleep quality as measured by a cutoff value of > 5 on the Pittsburgh Sleep Quality Index (PSQI); or
        - Pain, including headaches, upset stomach, and other forms of pain as measured by a cutoff value of > 3 on the 11-point numerical pain scale (NPS).
- Has access to the Internet and a smartphone.

Exclusion criteria

- Individuals with any health conditions that could hamper their participation in the Smart Health 3P platform, such as severe cognitive, visual, or hearing impairments.

You will be randomized to either the experimental or the waitlist control group based on the screening results. The experimental group will receive a 24-week intervention combined with an 8-week regular supervision phase (face-to-face or by telephone) plus a 16-week self-help phase. Participants will be recommended to receive either physical activity training, mindfulness-based intervention or energy conservation techniques based on their assessment

results. Besides, participants in the experimental group will be given a tablet with LiDAR motion sensor and full-body tracking sensor to capture real-time data on human body movements for accuracy and score calculation. Moreover, a commercial wearable sensor will also be given and participants are required to wear the sensor at all times to self-monitor their daily condition. The waitlist control group will receive the same intervention as the experimental group in Week 25 after the baseline assessment. During the waiting period, the control group will receive materials on the promotion of physical and psychological health prepared by the Department of Health.

Researchers will conduct face-to-face interview and assessment at baseline (T0), immediately after the completion of all supervised sessions (T1 at Week 8) and after the completion of the self-management phase (T2 after 24 weeks when the intervention has been completed). The assessments will include socio-demographics information, the Kessler Psychological Distress Scale (K10), the Brief Fatigue Inventory (BFI), the Pittsburgh Sleep Quality Index (PSQI), the Numerical Pain Scale (NPS), the Cognitive Emotion Regulation Questionnaire Short Form (CERQ-short), the General Self-efficacy Scale (GSS), the Depression Anxiety Stress Scales (DASS-21), Impact of Event Scale – Revised (IES-R) and steps count, active minutes, active zone minutes, hourly activity and stationary time, resting heart rate, heart rate zones, sleep conditions, including sleeping hours and stages, as well as stress management score collected by the commercial wearable sensor. These assessments will be used to evaluate the efficacy of the Smart Health platform to alleviate people's physiological and psychosocial distress under the influence of COVID-19.

In addition, each participant will receive a supermarket coupon of HK$100 as appreciation for his/her contribution after completing each time of assessment (HK$300 in total for three time points).

No risks will be involved during assessment phase of the research project. You are only required to answer questions specific to the assessment instruments. Possible side effects such as mild exercise-induced muscle tiredness may arise. If you feel any discomfort or muscle tiredness during the physical training, you have the right to suspend the study immediately and decide whether or not to receive further treatment depending on the circumstances.

You have the right to withdraw from the study at any time without being discriminated against, treated inhumanely and disrespectfully or penalised. All information will be kept strictly confidential and only Dr. Justina Yat-Wa Liu and delegated researchers will have access to the information. Your name will be coded and only delegated researchers will be able to identify the code. All information collected will be kept for 7 years until 2029. The collected data may be used for future studies, education and academic purposes. If you would like to know more details of this study, please contact Dr Justina Liu at 2766-4097 or via justina.liu@polyu.edu.hk. If you have any complaints about the conduct of this research study, please do not hesitate to contact Miss Cherrie Mok, Secretary of the Human Subjects Ethics Sub-Committee of The Hong Kong Polytechnic University in writing (c/o Research Office of the University) stating clearly the responsible person and department of this study.

Thank you for your participation.

Dr. Justina Yat-Wa Liu
Principal Investigator
School of Nursing
The Hong Kong Polytechnic University